

CHEEVER et al. Application No.: 09/493,480 PATENT

## APPENDIX B CLAIMS UNDER EXAMINATION

- 93. (twice amended) An isolated nucleic acid encoding a fusion protein comprising a HER-2/neu extracellular domain fused to a HER-2/neu phosphorylation domain, wherein the nucleic acid hybridizes under stringent conditions to the complement of a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:6, and separately to the complement of a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:3, and separately to the complement of a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:4, wherein the hybridization reaction is incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65°C, and wherein the protein is capable of producing an immune response in a warmblooded animal.
- 94. (previously once amended) The nucleic acid of claim 93, wherein the nucleic acid encodes a fusion protein comprising an amino acid sequence of SEQ ID NO:3 linked to an amino acid sequence inclusive of Gln 991 to Val 1256 of SEQ ID NO:2.
- 95. (previously once amended) The nucleic acid of claim 93, wherein the nucleic acid encodes a fusion protein comprising an amino acid sequence of SEQ ID NO:8 linked to an amino acid sequence of SEQ ID NO:4.
- 96. (previously once amended) The nucleic acid of claim 93, wherein the nucleic acid encodes a fusion protein comprising an amino acid sequence of SEQ ID NO:8 linked to the amino acid sequence inclusive of Gln 991 to Val 1256 of SEQ ID NO:2.



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- 97. (previously once amended) The nucleic acid of claim 93, wherein fusion protein comprises sequences that are linked via an amino acid linker.
- 98. (previously once amended) A viral vector comprising a nucleic acid of claim 93.
- 99. (previously once amended) A composition comprising the nucleic acid of claim 93, and a physiologically acceptable carrier or diluent.
- 100. (previously once amended) The composition of claim 99, wherein the composition is a vaccine.
- 101 (previously once amended) The composition of claim 99, further comprising an immunostimulatory substance.
- 102. (previously once amended) The composition of claim 99, wherein the nucleic acid is a DNA molecule.
- protein comprising a HER-2/neu extracellular domain fused to a fragment of the HER-2/neu phosphorylation domain, wherein the nucleic acid hybridizes under stringent conditions to the complement of a nucleic acid encoding the amino acid sequence of SEQ ID NO:7, and separately to the complement of a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:3, and separately to the complement of a nucleic acid sequence encoding the amino acid sequence encoding the amino acid sequence encoding the amino acid sequence of SEQ ID NO:5, wherein the hybridization reaction is incubated in a solution comprising 5x SSC at a temperature of 50-65°C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65°C, and wherein the protein is capable of producing an immune response in a warmblooded animal.
- 104. (previously once amended) The nucleic acid of claim 103, wherein the nucleic acid encodes a fusion protein comprising an amino acid sequence of SEQ ID

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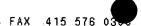
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NO:2.

NO:3 linked to the amino acid sequence inclusive of Gln 991 to Arg 1049 of SEQ ID

- 105. (previously once amended) The nucleic acid of claim 103, wherein the nucleic acid encodes a fusion protein comprising an amino acid sequence of SEQ ID NO:8 linked to an amino acid sequence of SEQ ID NO:5.
- 106. (previously once amended) The nucleic acid of claim 103, wherein the nucleic acid encodes a fusion protein comprising an amino acid sequence of SEQ ID NO:8 linked to the amino acid sequence inclusive of Gln 991 to Arg 1049 of SEQ ID NO:2.
- 107. (previously once amended) The nucleic acid of claim 103, wherein fusion protein comprises sequences that are linked via an amino acid linker.
- 108. (previously once amended) A viral vector comprising a nucleic acid of claim 103.
- 109. (previously once amended) A composition comprising the nucleic acid of claim 103, and a physiologically acceptable carrier or diluent.
- 110. (previously once amended) The composition of claim 109, wherein the composition is a vaccine.
- 111. (previously once amended) The composition of claim 109, further comprising an immunostimulatory substance.
- 112. (previously once amended) The composition of claim 109, wherein the nucleic acid is a DNA molecule.
- 113. (previously once amended) A method of making a fusion protein, the method comprising the steps of:



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- introducing into a cell an expression vector comprising a nucleic (a) acid according to claims 93 or 103;
  - culturing the transfected cell; and
  - (c) purifying the expressed fusion protein.
  - 114. (as filed) The method of claim 113, wherein the cell is a CHO cell.
- 115. (as filed) The method of claim 113, wherein the cell is cultured in suspension, under serum-free conditions.
- (previously once amended) The method of claim 113, wherein the 116. expressed fusion protein is purified by a two-step procedure, the procedure comprising:
  - (a) anion exchange chromatography; and
  - **(b)** hydrophobic chromatography.
- (as filed) The nucleic acid of claim 93, wherein the nucleic acid 117. encodes a fusion protein comprising an amino acid sequence of SEQ ID NO:3 linked to an amino acid sequence of SEQ ID NO:4.
- 118. (as filed) The nucleic acid of claim 93, wherein the nucleic acid encodes a fusion protein comprising an amino acid sequence of SEQ ID NO:3 linked to an amino acid sequence of SEQ ID NO:5.
- (as filed) The nucleic acid of claim 93, wherein the nucleic acid encodes an amino acid sequence of SEQ ID NO:6.
- 120. (as filed) The nucleic acid of claim 93, wherein the nucleic acid encodes an amino acid sequence of SEQ ID NO:7.
- 121 (as filed) The nucleic acid of claim 93, wherein the nucleic acid encodes a secreted fusion protein.

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- 122. (as filed) The nucleic acid of claim 103, wherein the nucleic acid encodes a fusion protein comprising an amino acid sequence of SEQ ID NO:3 linked to an amino acid sequence of SEQ ID NO:5.
- (as filed) The nucleic acid of claim 103, wherein the nucleic acid encodes an amino acid sequence of SEQ ID NO:7.
- (as filed) The nucleic acid of claim 103, wherein the nucleic acid 124. encodes a secreted fusion protein.
- 125. (new) The composition of claim 109, comprising an oil-in-water emulsion.
  - 126. (new) The composition of claim 125, comprising tocopherol.
- 127. (new) The composition of claim 111, wherein the immunostimulatory substance comprises 3D-MPL, QS21, or a combination of 3D-MPL and QS21.
- 128. (new) The composition of claim 111, wherein the immunostimulatory substance comprises 3D-MPL and QS21 in an oil-in-water emulsion.
  - 129. (new) The composition of claim 128, comprising tocopherol.
- 130. (new) The composition of claim 109, comprising a CpGcontaining oligonucleotide.

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